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March 23, 1999

Dockets Management Branch
HFA-305
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION
(ANADA SUITABILITY PETITION)

Veterinary Research Associates, Inc hereby submits this petition under Section 512 (n) (3) of the Federal Food, Drug and Cosmetic Act to seek permission to file an Abbreviated New Animal Drug Application which differs in strength and dosage form from the innovator product.

A. Action requested

Veterinary Research Associates, Inc seeks permission to file an ANADA for a generic equivalent of the innovator product PropoFlo Propofol Anesthetic Injection-10 mg/ml, NADA 141-098, Abbott Laboratories, which differs from the innovator product in strength and dosage form.

The innovator product is an emulsion containing 10 mg/ml propofol. VRA's proposed generic product is a clear solution containing 25 mg/ml propofol and consists of the following proposed formulation:

Propofol	25 mg/ml
N-Methylpyrrolidone	30% w/v
Propylene Glycol	40% w/v
Water for Injection	q.s. (~30% v/v)

B. Statement of grounds

Veterinary Research Associates, Inc proposes the change in dosage form for the following reasons:

1. The innovator formulation is an emulsion containing lecithin and soybean oil which has a history of serious problems including fatalities associated with microbial contamination in both human and veterinary use. The innovator product (which doesn't contain antimicrobial preservatives) can become an excellent media promoting microbial growth. Although the product is labeled as a single dose vial, because it is packaged in 20 ml vials, multiple use is encouraged, especially in small dogs. Because of this widespread problem, Phoenix Scientific, Inc has filed a Suitability Petition requesting permission to file an ANADA with the addition of a preservative.

2. The manufacturing of the innovator emulsion formulation is an expensive process which requires specialized equipment.

3. VRA's proposed proprietary formulation, JINAD 10-463, is a stable formulation which doesn't promote microbial growth. The formulation, although not tested, is likely to be bacteriostatic and fungistatic.

Veterinary Research Associates, Inc proposes to increase the propofol concentration from the innovator's 10 mg/ml up to 25 mg/ml for these reasons:

1. Based on an induction dose of 5.5 mg/kg, the proposed concentration of 25 mg/ml propofol gives a convenient dose rate equivalent to 1 ml/10 lbs body weight. Many veterinarians prefer to administer drugs based on ml per lb, 10 lb or 100 lbs body weight. Weighing an animal in lbs, converting to kg by dividing by 2.2046 and then determining the proper initial dose of 5.5 mg propofol per kg body weight requires multiple calculations which can lead to mistakes. Use of the proposed 1 ml/10 lbs body weight induction dose is simple and less prone to mistakes. The proposed 10 ml single-dose vial provides sufficient propofol to anesthetize a 100 lb dog or to anesthetize a smaller animal with sufficient propofol for maintenance dosage for an extended duration of anesthesia.

2. By increasing the propofol concentration, the carrier solvents injected are proportionately less, decreasing the volume injected and minimizing the risk of solvent toxicity.

C. Environmental impact

Veterinary Research Associates, Inc believes that this petition is subject to categorical exclusion under 21 CFR 25.24.

D. Economic impact

An economic impact analysis will be provided if requested after review of this petition.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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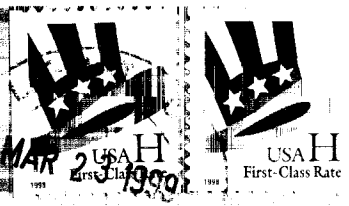

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